Tentative Approval Generic Zidovudine Oral Solution

The Food and Drug Administration (FDA) today, September 7, 2005, announced the tentative approval of zidovudine oral solution manufactured by Aurobindo Pharma LTD. Hyderabad, India. This product is the first tentatively approved generic version of Retrovir brand of the zidovudine oral solution (manufactured by GlaxoSmithKline). This oral dosage form of the drug is the first pediatric-friendly oral solution available for consideration for purchase under the President's Emergency Plan for AIDS Relief (PEPFAR).

Zidovudine is in the class of drugs called nucleoside reverse transcriptase inhibitors (NRTIs), which help keep the AIDS virus from reproducing. It is intended to be used with other antiretroviral agents for the treatment of HIV-1 infection. This product contains 50 mg/5mL of zidovudine in an oral solution.

Tentative approval means that although existing patents and/or exclusivity prevent marketing of this product in the United States, it meets all of FDA's quality, safety and efficacy standards for U.S. marketing.

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